

Applicants: Stefan Somlo and Toshio Mochizuki
Serial No.: 09/753,008
Filed: January 2, 2001
page 8

REMARKS

Claims 76-81 were pending in the subject application. By this amendment, applicants have amended claims 76 and 79, and added new claims 82-91. Accordingly, upon entry of this amendment, claims 76-91 will be pending and under examination.

Applicants maintain that the amendments to the claims do not raise an issue of new matter. Support for the amendments to claims 76 and 79 can be found at least in the previous version of the claims and *inter alia* in the specification at least on page 4, lines 20-23. Support for new claims 82-91 can be found *inter alia* in the specification at least on page 8, lines 13-32, and page 15, line 8, through page 17, line 3.

Applicants have amended the specification to (i) clarify that the subject application claims priority of parent and grandparent U.S. Application Nos. 09/385,752 and 08/651,999, (ii) add sequence identifier numbers (SEQ ID NOS), and (iii) refer to Figure 5A-5G in the Brief Description of the Figures. Applicants maintain that the amendments to the specification do not raise an issue of new matter.

Entry of the Amendments is respectfully requested.

Objections to the Specification

The Examiner objected to the specification (1) as unclear whether applicants claim priority of U.S. Application Nos. 09/385,752 and 08/651,999, (2) because the Brief Description of the Figures only refers to Figure 5 whereas there is Figure 5A-5G in the application, and (3) because nucleotide sequences on page 12 are missing SEQ ID Nos.

Applicants have hereinabove amended the specification to (1) clarify that the subject application claims priority of both U.S. Patent Application Nos. 09/385,752 and 08/651,999, (2) to refer to Figure 5A-5G in the Brief Description of the Figures, and (3) to add SEQ ID Nos. on pages 6 and 12.

Applicants: Stefan Somlo and Toshio Mochizuki
Serial No.: 09/753,008
Filed: January 2, 2001
page 9

Accordingly, reconsideration and withdrawal of these objections are respectfully requested.

Objections to the Claims

The Examiner objected to claims 76 and 79 for reciting “the *PKD2* gene”. Applicants have hereinabove amended claims 76 and 79 to recite “*PKD2* gene”. The Examiner objected to claim 79 for reciting “wherein the mutation comprises one or more deletion, insertion, point, or rearrangement mutations.” Applicants have hereinabove amended claim 79 to recite “wherein the mutation comprises a deletion, insertion, point, or rearrangement mutation.”

Accordingly, reconsideration and withdrawal of these objections are respectfully requested.

Rejections under 35 U.S.C. §112, First Paragraph

Claims 76-81 are rejections under 35 U.S.C. §112, first paragraph, as not enabled for the full breadth of the claims. The Examiner indicated that the claims are not enabled for methods comparing a *PKD2* gene from one species with a wild type *PKD2* gene from another species.

Applicants have hereinabove amended the claims to recite that the methods are directed to detecting the presence or absence of a mutation in the sequence of *PKD2* gene in a human subject, that the polynucleotide sample containing the sequence of *PKD2* gene is from a human subject, and that the wild-type *PKD2* sequence is a human wild-type *PKD2* sequence.

Accordingly, reconsideration and withdrawal of this ground of rejection are respectfully requested.

Applicants: Stefan Somlo and Toshio Mochizuki
Serial No.: 09/753,008
Filed: January 2, 2001
page 10

Rejections under 35 U.S.C. §112, Second Paragraph

a) Claim 76

Claim 76 is rejected as vague and indefinite because step (a) does not indicate that the polynucleotide sample has *PKD2* gene, because the claim does not indicate what gene has the mutations, and because the claim does not contain a step indicating that the goal of detecting the presence or absence of a mutation in the sequence of *PKD2* gene is reached.

Applicants have hereinabove amended claim 76 to recite that polynucleotide sample in step (a) contains the sequence of *PKD2* gene, that the gene mutations are of *PKD2* gene, and that the presence or absence of a mutation in the sequence of *PKD2* gene is detected.

Accordingly, reconsideration and withdrawal of this ground of rejection are respectfully requested.

b) Claim 79

Claim 79 is rejected as vague and indefinite because step (a) does not indicate that the polynucleotide sample has *PKD2* gene. Applicants have hereinabove amended claim 79 to recite that polynucleotide sample in step (a) contains the sequence of *PKD2* gene.

Accordingly, reconsideration and withdrawal of this ground of rejection are respectfully requested.

Obviousness-type Double Patenting Rejection

Claims 76-81 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of parent U.S. Patent No. 6,228,591 B1.

Applicants: Stefan Somlo and Toshio Mochizuki

Serial No.: 09/753,008

Filed: January 2, 2001

page 11

Applicants attach hereto a Terminal Disclaimer in compliance with 37 C.F.R. §1.321(c) in order to remove the double patenting rejection over U.S. Patent No. 6,228,591 B1. A fee of \$110.00 is required for submitting a Terminal Disclaimer, and a check including this amount is enclosed.

In view of the Terminal Disclaimer attached hereto, applicants respectfully request withdrawal of the double patenting rejection.

Return of Information Disclosure Statement Forms

On March 24, 2003, applicants filed an Information Disclosure Statement which included forms PTO/SB/08A and PTO/SB/08B. The Examiner returned a copy of form PTO/SB/08A, but not PTO/SB/08B, with the April 14, 2004 Office Action. A copy of the previously submitted form PTO/SB/08B is attached hereto.

Applicants request that the Examiner return a copy of form PTO/SB/08B signed by the Examiner to indicate that the reference listed on the form has been considered.

Applicants: Stefan Somlo and Toshio Mochizuki
Serial No.: 09/753,008
Filed: January 2, 2001
page 12

CONCLUSIONS

A check for \$368.00 is enclosed to cover (1) the \$258.00 fee for filing three independent claims in excess of the three previously paid for (\$86.00 per excess independent claim) and (2) the \$110.00 fee for filing a Terminal Disclaimer. No other fee is deemed necessary in connection with the filing of this Amendment. However, if any other fee is required to preserve the pendency of the subject application, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 01-1785. Any overpayment may be credited to Deposit Account No. 01-1785.

Respectfully submitted,

AMSTER, ROTHSTEIN & EBENSTEIN LLP
Attorneys for Applicants
90 Park Avenue
New York, New York 10016
(212) 336-8000

Dated: July 7, 2004
New York, New York

By 
Alan D. Miller, Reg. No. 42,889